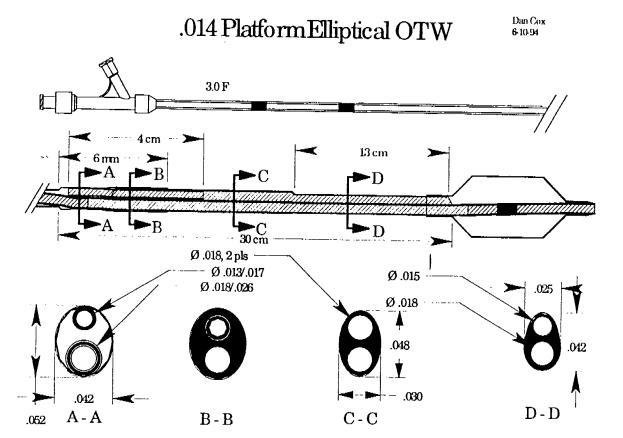
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## ACS HEART MODEL EVALUATION: Over-the-Wire Catheter

rc	pject Engineer			Wet	Di	Y:			
<u> </u>	nical Research Coordinator:	oller N	COVER			* .			
۵	ntrol: Catheter: Used								
	iding Catheter: 7F TE.	3.5 PG-	Guide: Win	o <u>Fraver</u>	5 <i>p</i>	ka sija			
_	ioniq. Canacas and an annual								
70	duct design/performance goals; 3;	0 F 0							
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4	tathen 640 Distal outer s	haft 3.9 F 1	6 2.7F	1.0 PEGOO	<del></del>				
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_									
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	comments. Acceptable, like	, , , , , , , , , , , , , , , , , , ,	၁	•	٥	3			
	Comments: /TCCRPTA.DIP , ILE	e bavel							
_									
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	3. Balloon to shaft	Ç Sarvicantv	Sameure	3	Somewhat	Springer			
	T SEECON IO STELL	Setter O	Baser O	Same As C	Worse O	/40/000 (3			
	C. Shart transitions:	Signational	Somewhat		Someone	Signalicarem Marse			
		Setter O	Sector O	3477-44	Worse C	٥ .			
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	arcs protty well.	<u></u>	· · · · · · · · · · · · · · · · · · ·						
	Flexibility of shaft:								
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		Q	5	3 7	9	9			
	B. Distal shart;	Sepationary Seasor	Somewhat Better	Sarre As	Somewrage Worse	Signalizaraty Wares			
	_	_ 🗢	3	ာ	0	3			
	Comments: A! SHE B!	Flexible	30th nize	-					

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5.	Esse of prep:	Ртед method:				
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	Comments:				· · ·	
<b>5</b> .	Inflation and deflation times:	Significantly Sector	Same-ne Setur O	Same As	Seminaring Witness	Sgraftcardy Worse O
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7.	General appearance of dilatation catheter during inflation and deflation (note bowing and folding):	Sgrafearity Batter O	Samura Bosov O	Saprino Adi	Seriouvida Worse O	Significantly Worse
., 4	Comments			······		
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	commence: Tales hight radiu	s real w				
9,	Pushability:	Significantly Satter O	Somewhat Senter O	Sarrey As	Somewhat Worse	Sq <del>uicardy</del> Wares
	comments: Good 1:1 tra	nsmission				
10.	Guide back out:		Y=	···	No	-
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	commens. No quide novemen	F lightly	seated in	046 /PSION		
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	rtij comments;					
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	v	Recommend	i For Animai Studie	ts?	N/A	
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Advanced Cardiovascular Systems. Inc.

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ACS HEART MODEL EVALUATION: Over-the-Wire Catheter

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EI		xial Proximal 029/1049 to 1024	3.0 F PER		/PE innu	mem ber
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5.	Esse of prec:	Prep method:				
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	Comments:		·			<u> </u>
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	comments: Can feel proximal	transition be	ut 5till to	orks well		
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			<del></del>			
2.	Guide back out;		Y==		No	
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t.	Guide wire movement:	Significantly	Sarrang		Somerner	Sandanay
	Comments: Sticky	Better O	0	Seme As	<b>7</b>	Worse O
	Ilmensions (list size and area):					
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, li	ght petermance Edge Par	coovie/	in wire	moupment-		
		Recommend Fo	or Animai Studies?	<del></del>		
·	Yes		or Animal Studies?		N/A	

6/24/94

Date:

6/21/94

Title:

Coax w/PEEK - Elliptical Distal (with a 100% HDPE a 75/25 HDPE/LLDPE and a 83/13/4 HDPE/LLDPE/GRAPHITE distal elliptical)

Objective:

To evaluate these catheters to determine if the stiffer materials

(100%HDPE and 83%/13% 4% HDPE/LLDPE/GRAPHITE) perform better than

the softer 75/25 material. I.e., prevent prolaspe

Procedure:

Note: Ref drawing for dimensions

Tooling:

.011, .017, .018, .024, .026, .028 .031 and .040 Teflon coated mandrels.

.025, .031, .039, 043 and .048 Teflon capture tubing.

Razor blades, Hot box, and Induction heater

Materials:		
Description	Part Number	Comments
Elliptical dual lumen	N/A R&D	75/25 Alathon/LDPE
Elliptical dual lumen	Ext. # 10-465-T	100% HDPE
Elliptical dual lumen	Ext. # 12-194-B	83% HDPE w/13% LLDPE +
Emparation 1		4% Graphite
ĪM	Ext. # 13-88-A	Graphite
Intermediate shaft	Ext. # 12-083	Alathon 6210
IM	Ext # V-466-1	Graphite
Stiff Shaft	Vendor# 02-149	PEÉK 381G
Shaft adaption cup	MC500419-02	N/A
IM adaption cup	MC500296	Standard ACS part
Centerport	MC500323	Standard ACS part
Nose cone	MC500319	Standard ACS part
Two arm	RM500219	4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4
Distal tip Material	Ext. # V-466-1	Graphite
Balloon	3.0mm Edge	PE 600
Shrink tubing	SA500082-03	
Gold Bands	RM500340	
Loctite	RM60563	414
Loctite	RM60124	420
Loctite	RM60562	350

### Assembly Instructions: (Distal Elliptical)

- Cut approximately 40 cm of the elliptical shaped tubing.
  Place a .018" Teflon Mandrel in the guide wire lumen and a .015 Teflon mandrel in the inflation lumen.
- Neck the material down to .026 x .045  $\pm$  .001.
- Parameters: Temp = 270 f Stretch Speed = 200 Nozzle Speed = 600 Dwell Heat = 5 Dwell Cool = 1 Length = 15cm Trim necked portion to 10cm.
- Cut a 2-3mm notch in the inflation lumen at the distal tip of the necked material. (fig 1)

Cut the graphite to approximately 20 cm.
Neck the graphite to .021 OD using an autonecker.
Parameters: Temp = 290° f Stretch Speed = 400 Nozzle Speed = 200

Length = 10cm Slide the gold band over the necked portion.

- Recover the graphite up to the gold band using a .024 capture tube and Hot Box, at 350° f

Using a .028" sheath and a Hot Box at 350° f and 60-70 psi expand 1 cm. Remove material from the sheath and trim to 5mm.

- Insert a .017" Teflon mandrel through the graphite and the guidewire lumen of the elliptical material.

- Fuse the graphite to the elliptical dual lumen using a .026 capture tube and Hot Box at 350° f

#### Balloon Seal:

Expand proximal balloon shaft in a .048 ID capture tube.

- Trim to 7mm

Insert a .015 mandrel into the inflation lumen.

Slide .039 oval split sheath onto catheter.

Slide sheath over proximal portion of the balloon and heat seal at 350° f

Flatten with a flat smooth block

Remove inflation/deflation mandrel.

Tip seal using a "Balloon Buncher Tip Sealer"

Parameters: Temp = 340' f Hot Stretch = 0003 Dwell = 0006 Pretension = 0006 Micrometer setting = 0.675"

#### Proximal End:

Trim assembly from the gold band to the proximal end of the elliptical shaped tubing 35cm.

Insert two-.018 Teflon coated mandrels into both lumens.

Neck using an autonecker.

- Parameters: Temp = 270'f Stretch Speed = 200 Nozzle Speed = 600 Dwell Heat = 5 Dwell Cool =  $\hat{1}$  Length = 1.5cm (trim to 1cm)
- Remove the mandrels and Insert a 4.5cm piece of Polyimide into the inflation lumen. Tack the Polyimide into place with a drop of Loctite 420.

#### Inner Member Assembly:

Cut a 125cm piece of Graphite inner member material.

Insert a .017 mandrel through the Graphite.

- Neck the Graphite to .021 OD using an autonecker.

  Parameters: Temp = 290' f Stretch Speed = 400 Nozzle Speed = 200 Length = 1cm (trim to 4mm)
- Flare the guidewire lumen with a .025 mandrel 1mm.
- Insert the necked graphite into the flared guidewire lumen.

Insert a .012 mandrel into the Polyimide.

- Bond the Graphite to the dual lumen elliptical material using a .039 oval capture tube or silicone
- Parameters: Temp = 350° f (Hot Box)
- Remove the .012 mandrel from the Polyimide.

#### Proximal Shaft Assembly:

Cut a 110cm piece of PEEK.

Expand one end of the PEEK, 1cm in a .043 capture tube using a Hot Box at 350° f (ID should be .039)

Trim the expanded portion 5-6mm

Cut the PEEK 102 cm from the proximal end of the expanded portion.

Slide the PEEK over the Graphite IM and elliptical material and bond using Loctite 420 Note: do not allow the adhesive to wick into the Polyimide tubing. Note: do not force the unexpanded PEEK over the Inflation lumen.

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#### Two-Arm Assembly:

Trim the graphite 3cm from the proximal end of the PEEK.

Slide the nosecone, outer member adaption cup, and twoarm over the PEEK.

Bond and inner member adaption cup to the graphite using 3.0 mm x 1cm shrink tubing on a Hot Box at 350° f. Note: use a .018 Teflon mandrel in the graphite.

- Attach the IM cup to the twoarm with a centerport.

- Slide the outer member cup up toward the twoarm and wick in UV cure Loctite 350

- Attach the OM cup to the twoarm and tighten the nosecone and centerport

- UV cure on each side of the nosecone for 50 seconds.

#### Final Assembly:

- Trim tip to 3.0mm
- Tip Sand
- Microglide and Sheath

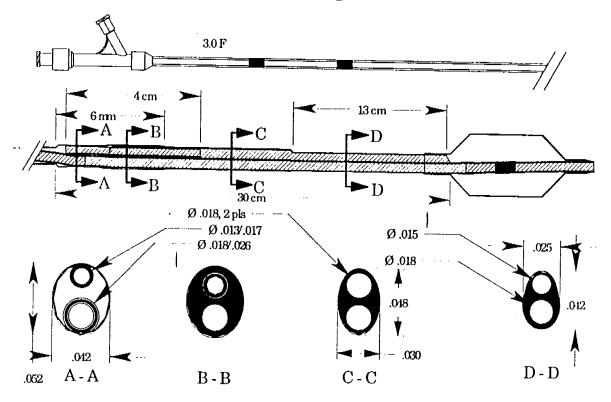
Conclusion: The 100% HDPE and the 83/13/4 blend performed better than the 75/25 LLDPE catheters. The 83/13/4 blend tracked over the wire with ease. It was mentioned that "this is the best I have seen in a while" the guidewire movement was rated 3.75 on a scale of 1 -5 with 5 being the best. Both the 100% and the 83/13/4% blend had good push however the 100% was slightly better. The 100% HDPE and the 83/13/4% blend seem to follow the wire and was less prone to prolapsing whereas the 75/25% seem to press up against the walls of the artery. (for more details see heart model evaluation notes)

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# .014 Platform Elliptical OTW

Dan Cox 6-10-94



E-COM 6/24/44



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#### ACS HEART MODEL EVALUATION: Over-the-Wire Catheter

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	nical Research Coordinator:		M-O pon			
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_	quet design/performance gosts;					
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# ACS HEART MODEL EVALUATION: Over-the-Wire Catheter

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	(note bowing and folding):						
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Э.	Pusnability:	Significantly	Same		Samerine	Significantly Warte	
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	end outh						
١٥.	Guide back out:		Yes		No	-	
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## ACS HEART MODEL EVALUATION: Over-the-Wire Catheter

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	ical Research Coordinators				and the second	·
	umi Cathelec Used					
	ding Catheter	Acceptance and the second seco	Guide Wit	92		
	ouct design/performance goals:	cal lumen is	75% HOP	= /25% 11	LOPE /wh	( <del>/-</del> )
_ <u></u>	THE AS (I) PRICEP! AS	a. idilleri 12	7 - 1 - 1 - 1 - 1			
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2.	Tip length:	Sector 3	Seter O	Same As	Worse	3
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3.	Smoothness of transition;					
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	3. Batloon to shart:	Sandandy	Sanware	•	Someone	Synfamily
	3. SWINGER IN SHAPE	3eter O	3	Serie As C	C	3
	C. Shart transmons:	Significantly Sector	Sprawnit Setter	Same As	Someway	Signal Carrier Mortes
	a Bi formal and	cand smooth	<b>.</b>	3	၁	à
		mooth best	Lall			
4.	Flexibility of snart;					
٠.	A. Proximal shart	Signature	Samuel	5 h.	Sommered	Signal-control
		3ester O	3000	Same As O	3	3
	3. Distal shart	Signal and the Section of the Sectio	Samewrest Secur	Same As	Somewhat 'Horse	Sgranzerty Water
	comments: B: Less she	U tran O ob	out same	as (2)		
	Comments: No Calaba State					

Mahory 6/24/94

(See Reverse)

white

6/24/94

s.	Ease of prep:	Prea method:			<del></del>	<del></del>
1		Squitanty	Servense	h-	Semestrat	Systems
		3	3	3	0	3 3
i	Comments:					
			<u> </u>			
3.	inflation and deflation times;	Sgnécaray	Sement		3-7	Significantly
7.		3 <del></del>	3 <del>,24,</del> O	Same As O	Ware	Worse
· .		Inflation time:	· · · · · · · · · · · · · · · · · · ·		(are:	
]		Contrast & dilution	مت در و	Indation		
1	Comments;		•			
	Commence.					
<u> </u>						
7.	General appearance of dilatation catheter during initiation and deflation (note bowing and folding):	<del>Significantly</del> Beter O	Santa-Per Beder O	Sapras As G	ŞarkemfdE Worse O	Significanty Works O
	Comments:					
				· · · · · · · · · · · · · · · · · · ·	<del> </del>	
a.	Trackability:	Sonfrante	Somewhat		Springer	Significantly
_		deter Q	3	Same 44	<del>/////////////////////////////////////</del>	Wares C
	comments: About rare as	1 Net a	s good as	(2)		
			0			
	The manifest of the same of th	Synfactory	Somewhat		Somewhat	Sanicerov
9.	Pusnacility:	3eter	Secor	Same As	Warne	Werse
	comments: Push is gratty	cond Or	esnit square	all in w	egel like	i when
	Las Dush	<i>J</i>	-7-			
<u> </u>						
10.	Guide back out:		Yes			-
		Significantly Setter	Sorteurez Setter	Same As	Sorre-Nex Worse	Signal Committy Waters
	_	o	•	Ç	9	9
	Comments;					
11.	Guide wire movement;	Significantly Section	Sarrana Sarran	Same As	Somewhat Worse	Significanty
	0 4	0	, 7	-0	3	9
	commence Pretty good.	3.75 h	septa!			· · · · · · · · · · · · · · · · · · ·
			······································			
12_	Dimensions (list size and area):					
		<del></del>				
				<del></del>		<del></del>
13.	Old product meet design goals?		Yes		**	_
Ov+	rail comments:	sian in dia lins + lesian (	garal but	atheter	squared ol	2 .h
	<del></del>	Recommend	For Animal Studies	?		
	Yes		No		N/A	_
		<del></del>				

Robert 194 2

6/24/94

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PROPERTY OF ADVANCED CARDIOVASCULAR SYSTEMS, INC.



# Advanced Cardiovascular Systems, Inc. 3200 Lakeside Drive

P.O. Box 58167

Santa Clara, CA 95052-8167

NAME ERIC DEPT. \_ 1220 LAB. NOTEBOOK NO. ISSUE DATE -RETURN DATE -

RETURN TO DOCUMENT CONTROL FOR ARCHIVING.

5/25/94

Title:

Shaft Material Evaluation

Objective:

To evaluate various potential shaft materials

Materials:

EVAL Extrusion # 12-143A, EVAL Extrusion # 12-142A, AERN Nylon Ext # 11-221-1, Grivory Nylon Ext # 10-547-6, Grivory Nylon Ext # 10-548-1, PPS Ext # 10-556-1, Isoplast Ext # 10-531-1, PEEK 381G and PES Ext# 10-576-1

Procedure:

Rupture test 10 samples of the EVAL material and 5 samples each of the other materials. Parameters: Water Temp=37degC, Start Pressure=60psi, Increments=15psi, Hold time=15sec

#### Results:

Material	Ext #	ID/OD	Average Ru	pt	Std Dev	!	Ti	1	ſ
EVAL	12-143A	.017/.021		217.5	14.5773	8	<del>                                      </del>	<del></del>	1
EVAL	12-142A	.032/.038			6.324555			<del></del>	+-
AERN NYLON		.031/.038			8.2158384		<del>                                     </del>		<del>i                                     </del>
GRIVORY NYLO	N 10-547-6	.032/.039			8.2158384			<del></del> -	<del>                                     </del>
GRIVORY NYLO	N 10-548-1	.018/.025			8.215838-		<del>                                     </del>		<del> </del>
ISOPLAT	10-531-1	.031/.038			16.431677		<del>                                     </del>	<del></del> -	<del> </del>
PPS	10-356-1	.031/.038			8.2158384		<del>   </del>	<del></del>	
PES	10-576-1	.032/.039	i	5001			<del>                                     </del>	<del></del>	+
PEEK	ΝA	.032/.038		500		) i	-		
Material	Sample #	Puorum	Material			D	1.		
EVAL (Inner Men		210	EVAL		Sample #	Rupaire	Material	Sample #	
E . r it. (miner . victo	2		EVAL		1			. 1	
	3	210	+		2			2	
	4	210			3			3	
	5	210			4			4	
<del></del>	1 6	210	<del></del>		5			5	
	7	210	<del></del>	<del></del>				6	
	8	210	<del>                                     </del>					7	
	9	225	<del></del>	-	9			. 8	
	10	225	<del> </del>	- 1	10			9	
	101		+	<del>-i</del>	10	120	<del>                                     </del>	10	<u> </u>
Material	Sample #	Rupture	Material		Sample #	Rupeare	Material	Sample #	Ruomre
GRIVORY 547	1	405	GRIVORY	548	1	500	PEEK	1	
	2	420		Ī	2	500		2	500
	1 3	405			3	500	1	3	
	41	420	.!		41	500		4	
<del></del>	5	420			5	500		5	500
				1				<u> </u>	
laterial	Sample #	упране	Material	S	ample#	Rupture	Material	Sample #	Rupture
SOPLAT	1	375	PPS		ti	405	PES	1	500
<del></del>	2	375			2	405		2!	500
	31	405		1	31	420	T	3	500
	4	405		1	4	420		41	500
	5	375	-		56	405		51	500

Date:

5/27/94

Title:

PEEK To Elliptical Transition Development

Objective:

To evaluate various concepts for improving the transition from the PEEK outer

shaft to the elliptical distal dual lumen.

Materials:

Graphite Extrusion V-466-1, PEEK 3816, HDPE SA200247, Alethon Extrusion

12-083, Stainless Steel .007>.003 mandrels, Polyimide "Hudson" .013 x .017, and Loctite 414

Procedure:

Concept 1

PEEK to Elliptical. Insert two .018 Teflon coated mandrels into the elliptical tubing and neck using a hot box at 350F. Trim the necked portion to 5mm remove one of the mandrels and insert a 4 cm piece of polyimide tubing inside that lumen, wick in some adhesive to hold it in place. Bond the graphite to the other lumen with a but joint using an .026>.042 step sheath at 350f. Flare one end of the PEEK to an ID that will allow it to fit over the necked elliptical tubing. Trim the PEEK to 5mm and bond it to the elliptical tubing using Loctite 414.

Concept 2

PEEK to Elliptical with Intermediate Shaft. Insert two .018 Teflon coated mandrels into the elliptical tubing and neck using a hot box at 350F. Trim the necked portion to 5mm remove one of the mandrels and insert a 4 cm piece of polyimide tubing inside that lumen, wick in some adhesive to hold it in place. Bond the graphite to the other lumen with a but joint using an .026>.042 step sheath at 350f Cut a 3cm piece of HDPE flare one end so that it fits over the elliptical tubing. Using a .045 Teflon capture tube heat bond the HDPE to the elliptical tubing. Flare one end of the PEEK to an ID that will allow it to fit over the HDPE. Trim the PEEK to 5mm and bond it to the elliptical tubing using Loctite 414.

Concept 3
PEEK to Elliptical with .007>.003 tapered mandrel in the inflation lumen. Insert two .018 Teflon coated mandrels into the elliptical tubing and neck using a hot box at 350F trim to 5mm remove mandrel from one of the lumens and insert a 4 cm of tapered mandrel inside that lumen wick in some adhesive to hold it in place. Bond the graphite to the other lumen with a but joint using an .026>.042 step sheath at 350f. Flare one end of the PEEK to an ID that will allow it to fit over the necked elliptical tubing. Trim the PEEK to 5mm and bond it to the elliptical tubing using Loctite 414.

Conclusion:

Concept 1 was easily assembled and had a fairly good transition from PEEK to elliptical due primarily to the Polyimide in the inflation lumen; the joint was smooth and had an OD of .040x.046. Concept 2 required additional steps to build and yet it was inconclusive about which had a better transition. The OD measured .040x.047. Concept 3 had an improved transition over the first two however it was far more difficult to assemble and the wire was too large and could possibly impede deflation.

Date:

5/27/94

Title:

PEEK to Elliptical Intermediate vs No Intermediate Shaft

Objective:

To compare and evaluate the performance of a PEEK to elliptical OTW catheter with and

without a intermediate shaft.

#### Procedure:

Tooling:

.011, .017, .018, .024, .026, .028 .031 and .040 Teflon coated mandrels. .025, .031, .039, .043 and .048 Teflon capture tubing.

Razor blades, Hot box, and Induction heater

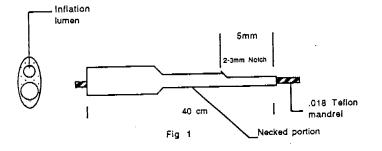
Materials: Comments Part Number Description 75/25 Alathon/LDPE Ext # 12-110A-Elliptical dual lumen Alathon 6210 Ext # 12-083 Intermediate shaft Ext. # V-466-1 Graphite IM PEÉK 381G Vendor# 02-149 Stiff Shaft N/A MC500419-02 Shaft adaption cup Standard ACS part MC500296 IM adaption cup Standard ACS part MC500323 Centerport Standard ACS part MC500319 Nose cone RM500219 Two arm Graphite Ext # V-466-1 Distal tip Material PE 600 3.0mm Edge Balloon \$A500082-03 Shrink tubing RM500340 Gold Bands 414 RM60563 Loctite 420 RM60124 Locute 350 RM60562 Loctite

# Assembly Instructions: (Distal Elliptical) - Cut approximately 40 cm of the elliptical shaped tubing.

Place a .018" Teflon Mandrel in the guide wire lumen and a .015 Teflon mandrel in the inflation lumen. Neck the material down to .026 x .045 +/- .001.

Parameters: Temp = 270'f Stretch Speed = 200 Nozzle Speed = 600 Dwell Heat = 5 Dwell Cool = 1 Length = 15cm Trim necked portion to 10cm.

Cut a 2-3mm notch in the inflation lumen at the distal tip of the necked material. (fig 1)



#### Distal Tip:

Cut the graphite to approximately 20 cm.

Neck the graphite to .021 OD using an autonecker.

Parameters: Temp = 290 f Stretch Speed = 400 Nozzle Speed = 200 Length = 10cm

Slide the gold band over the necked portion.

Recover the graphite up to the gold band using a .024 capture tube and Hot Box, at 350° f

- Using a .028" sheath and a Hot Box at 350° f and 60-70 psi expand 1 cm. Remove material from the sheath and trim to 5mm.

- Insert a .017" Teflon mandrel through the graphite and the guidewire lumen of the elliptical material.

- Fuse the graphite to the elliptical dual lumen using a .026 capture tube and Hot Box at 350° f

#### Balloon Seal:

Expand proximal balloon shaft in a .048 ID capture tube.

- Trim to 7mm

Insert a .015 mandrel into the inflation lumen.

Slide .039 oval split sheath onto catheter,

Slide sheath over proximal portion of the balloon and heat seal at 350° f

Remove inflation/deflation mandrel.

Tip seal using a "Balloon Buncher Tip Sealer"

- Parameters: Temp = 340° f Hot Stretch = 0003 Dwell = 0006 Pretension = 0006 Micrometer setting = 0.675"

#### Proximal End:

Trim assembly from the gold band to the proximal end of the elliptical shaped tubing 35cm.

Insert two-.018 Teflon coated mandrels into both lumens.

Neck using an autonecker.

- Parameters: Temp = 270 f Stretch Speed = 200 Nozzle Speed = 600 Dwell Heat = 5 Dwell Cool = 1 Length = 1.5cm (trim to 1cm)
- Remove the mandrels and Insert a 4.5cm piece of polyimide into the inflation lumen. Tack the polyimide into place with a drop of Loctite 420.

#### Inner Member Assembly:

Cut a 160cm piece of Graphite inner member material.

Insert a .017 mandrel through the Graphite.

Neck the Graphite to .021 OD using an autonecker.

Parameters: Temp = 290 f Stretch Speed = 400 Nozzle Speed = 200 Length = 1cm (trim to 4mm)

Flare the guidewire lumen with a .025 mandrel 1mm.

Insert the necked graphite into the flared guidewire lumen.

Insert a .012 mandrel into the polyimide.

Bond the Graphite to the dual lumen elliptical material using a .039 oval capture tube or silicone gel tubing. Parameters: Temp =  $350^{\circ}$  f (Hot Box)

- Remove the .012 mandrel from the polyimide.

#### Proximal Shaft Assembly:

Cut a 110cm piece of PEEK

Expand one end of the PEEK, 1cm in a .043 capture tube using a Hot Box at 350° f (ID should be .039)

Trim the expanded portion 5-6mm

Cut the PEEK 102 cm from the proximal end of the expanded portion.

Slide the PEEK over the Graphite IM and elliptical material and bond using Loctite 420 Note: do not allow the adhesive to wick into the polyimide tubing. Note: do not force the unexpanded PEEK over the Inflation lumen.

Two-Arm Assembly: - Trim the graphite 3cm from the proximal end of the PEEK.
- Slide the nosecone, outer member adaption cup, and twoarm over the PEEK.
- Bond and inner member adaption cup to the graphite using 3.0 mm x 1cm shrink tubing on a Hot Box at 350° f. Note: use a .018 Teflon mandrel in the graphite. Attach the IM cup to the twoarm with a centerport. - Slide the outer member cup up toward the twoarm and wick in UV cure Loctite 350 - Attach the OM cup to the twoarm and tighten the nosecone and centerport - UV cure on each side of the nosecone for 50 seconds. Final Assembly: - Trim tip to 3.0mm - Tip Sand - Microglide and Sheath Conclusion: Note: the Catheters built with an intermediate shaft were built by Kim Nugyen ref Lab notebook # 1152. The Catheters were compared in a heart model and it was determined that there was little difference in the two catheters performance, however neither catheter performed very well in comparison to our coaxial design. The proximal balloon seals were perceived as stiff and having an abrupt transition. Recommendation: Rebuild using the "no intermediate shaft" and improve the proximal balloon seal stiffness Recommendation: Repulse in a heart model. REF: heart Model Results Next Pasa 2.W 1-15-94



# ACS HEART MODEL EVALUATION: Over-the-Wire Catheter

Product 014 Platform 0		Dates_	5/20/94	<u> </u>	
Project Engineer <u>Dom</u> (			Wet:	The Short	
Clinical Research: Coordinator	<del>Ron</del> Se	<i>yna</i>		- A	Dry <del>.</del>
Control Catheter Used:					
Guiding Catheter 7F JL4	PG	Guide: V	Vire::::		
Product design/performance goals:					
COAXIAL OTW PER	EK posini		1.CL .	1 0+ 1	
Alathan 6210 distal shat	EK prizina + 2.7 F	0EG00 3.0	non Halow	<u>ite PE in</u>	inth wow
				<u> </u>	
1. To softness:					
	Significantly Bester	Someway Segar	Sarray Ag	Sommung Warne	Syntax
comments Nice taper,	imeeth	•	٥	0	o
Tip length:	Signation				
	Better	3een.	Same As	Someone Worse	Sgrafgen
Comments,	<b>.</b>	3	•	0	3
. Smoothness of transition:					
A. Distal to to balloon:			**		
Nice Folding	S <del>grancardy</del> Batter	Somewner Secur	Same to	Samewag	Sgrifern
S. Salloon to snam:	•	9	337	O .	Warse
Can feel transition	Signalearuy Beter	Servering		Samurage	Santan
•	٥	-	Same As O	Worke	Marsa
C. Shaft transitions:	Signalizatory	Somewhat		S	<b>.</b>
Can feel AEEK/AE junction	3ecar O	Sector O	Sarte As	Moreo	Sqrainger, Warte
Commence Transitions notices	able but ,	net a prob	lem	•	۰
					<del></del>
Flexibility of shaft:	-	<u> </u>			
A. Proximal share	Sontanie	<b>9</b>			
	<b>Better</b>	intering inter	Same As	Somewhere	Symicanus
3. Distal share	<b>O</b>	0	0	0	C Worse
	Significantly Secur	Someone	_	Someone	Sandanov
comments: Very nice	٥	3	Same As O	Wares Q	Worke
Comments: VC 9 MICE				•	a
<del></del>				<del></del> -	
				<u> </u>	

5. Esse of prep:	Preo memos:				
	Significantly Sector	Sony-ner Boowr	Same As	Sameurus Warns	Symicanity
comments: Fine	<u> </u>			<del></del>	<u> </u>
. Inflation and deflation times:	Syntaxy	Santoning			
	Second C	Genter O	Serve As	****	Signal Company Whomas O
<b>.</b> 1	Inflation time: Contrast & dilution:		Oeflagor	<u> </u>	
comments: No bowing					
7. General appearance of dilatation catheter during inflation and deflation	Signalicanusy Bester	\$money 2		Surre-nu	Signaturary
(note bowing and loiding):	•	<del></del>	Same As	3	Works
Tracksbillty:	Signalizarusy Besser O	Section 1	Saltu As	Some-ring Warter	Sgratcovay Worse
comments: TIP came aroun		cely. Too	k contour	of wire	nicely
Pushability:	Springer	Someone			
comments: Very nice A	Har 8 atm	8.44. 0	Same As	Whites	Significantly Wante Q
and with support got		.60 sec 1	n support	got 70%	into lesion
Suide back out:	<b>5</b> -4	Yes	······································	M=	· · · · · · · · · · · · · · · · · · ·
a. Cill1-4 1	Significantly Season S.L. I.C. Cartes	Someonig Bester	Sarre As	Somewhat Works O	Sig <del>nalicariay</del> Worms C
commons: Fully sheathed	Beir (.04	3) with light	t guide sup	opa-t	
illide wire movement:	Signationary Sector	Section 1	Sam- 4a	Sameung	Squicardy
commence Intally smooth	Э	peavier in	septal	5	O
Imensions (flat size and area);					
			<u> </u>		[
product meet design goels?	,	Yes		¥a	
commence: of nine out on with	hard pus	hing		· · · · · · · · · · · · · · · · · · ·	
it to kink and prolapse	like (D) ex	cerept a 1	ot more a	1, PAZalt to	prolapse
	Recommend For	Animai Studies?			
Yes		o		N/A	
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# ACS HEART MODEL EVALUATION: Over-the-Wire Catheter

G	uiding: Catheter:		Gulde: WI	re=		
Pro	Coxial proximal PE 75% HDPE/25% LLOPE P	EK outer sho	eft, graph	Te PE inn	er membe	
	13% MDPE/23% LLDPE @	Ilipital distal	shaff 3.0	ma PE60	0	
1.	Tip softness:	Septimenty Batter O	Somewhat Seater	Same As	Someone Warse	Significan Works
	Comments:					
2	Tip length:	Signification Bester	Somewhat Sester	Sarray As	Serrowner Worse	Significan
	Comments:		0	<u>×</u>	<u> </u>	0
١,	Smoothness of transition:				<u> </u>	
k	A. Distal to to balloon: bt as nice as D in fold	Significantly Setter Q	Somewhat Setter	Same As	Somewhat Worse	Significanii Worse
5~	3. Balloon to shall bulky to shaff	Significantly Compared 0	Someone: Boder	Same As	Santanana Works	Significant Worse
	Nice, smooth	Significancy Better O	Somewher Sector :	Same As	Someway	Significano Werse
	Comments: B		abrupti	ness, not alal	<u> </u>	•
	Flexibility of shart:					
•	A. Proximal snart:	Signalicanally Batter . C.	Somewher Sector	Sattle As	Statements Warne	Significantly Weree
	B. Cisual snart	Significancy Better	Someone	Same As	Stantowning Warse	Signaturary Warran
(	Comments: B: A 1,1410 more	florix la a	o .	1 /20 +4	a	3

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5.	Ease of prep:	Prep method:				
		Significantly Sector	Seme-rug Semer	Same As	Somewhat Warne	Stjerkensky Warne
1	comments: Fine	э	٥	0	၁	3
5.	inflation and deflation times:	Stantinger				
		Bactur	3	Sainten As.	Wares	Signatura Maria
		Inflation time:		Deflation	tme: 8 se	<u>د</u>
	0	Contrast & dilution:		indapon	device;	
	commence Bowing at 8	atm like (	3)		<u> </u>	
						<del></del>
7.	General appearance of diletition catheter during inflation and deflation	<del>Signaturay</del> Setter	Same-ner Same-	Sama da	Salitorial	Squicaray
	(note bowing and folding):	•	<u> </u>		" <del>。</del>	0
	Commence:	· · · · · · · · · · · · · · · · · · ·		<del></del>		
8.	Trackability:	Significancy Sector	Servenne Beter	Same As	Someone	Systems
	comments: Proximal seal	was stiff	المالية المالية	go around b	end into	رة رو
	Does not hug wire	jike O	) Old As7	around b	ena /n <del>/</del> o	septal
9.	Pushability:					
<b>J</b> .	ruminosty,	Significantly Setter	Selecting Select	Same As	Someone Worse	Significantly Warse
	comments: Good Fully she	tred wand	2 SUPPON	+, After .	Pahn got	Prot l
	balloon into 045 lesida. G	rot all Me w	ay in with	guide supp	c+,	
10.	Guide back out:		Y=			
		Signalicanity Sector	Samuel	_	Somewhat	- Signicanty
	- Izaki II.	ာ်	1 0	Same As	. 0	Warse Q
	Commons: Lightly seated }	ust got ha in	to 1851an (D	<u>43)                                    </u>		<del></del>
	A					
11,	Guide wire movement:	Significantly Better O	Saltening Beter	Serre As	Somewhat Worse	S <del>grateway</del> Weren
	commence Slightly worse	Than (1)	•	•	၁	٥
12	Ofmensions (flat size and area);					
		-		<del></del>		
	<u> </u>					
13. (	Old product meet design goals?		Y	,	*•	
	ill comments:	1 (4 :		, .		
<u>K Pf</u> Anc	t publing until distal	shaft prola		went into septal	circ and	LAO
	TARREST TARREST IL	10.2 STHEIR IN	162120 10 Z	epiai		
	Vaa		r Animal Studies?			
	Yes		¥o <u></u>			
000	ACTICIE ONE	× 1.1	2/	, /		
<i></i>	PATTESTS.CMS		/	6/011	44	: 1/18/92

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# ACS HEART MODEL EVALUATION: Over-the-Wire Catheter

Project Engineer CoX	A CONTRACTOR OF THE PROPERTY O		TT 64	Or	у <del>.</del>
Clinical Research Coordinator.	600 (3 C.				<u>*                                    </u>
Control Catheter Used					
		Guide: Wil			te dist.
Gulding: Catheter:					
Product design/performance goals: Same as (2) except	has 10 cm in	termediate	Alahon stif	Rhaft bet	wpen
elliptical distal and	PEEK 3.0	nm PE600			
1. Tip softness:	Significantly	Samuela		Server	Significa
	Beter Q	Sector O	~	5	0
·· comments Nice taper					
2. Tip length:	Signalization Bester	Speciment Sector	Same As	Squarement Worse	Signate Warn
comments A little sh	oter -	• • • • • • • • • • • • • • • • • • •			
Comments. 77			· · · · · · · · · · · · · · · · · · ·	·	
3. Smoothness of transition:					
A. Distat up to battoon:	Significantly Supple	Somewhat Reser	Same,As	Somewhat Wares	Signific Work
	0	3	×	<b>5</b>	O Sanés
3. Balloon to snart	Significantly Secon	Ş <u>ameningi</u> Şafter	Same As	Ware	Wen
Like 3	0	Ç	<b>э</b>	· **	ن جست
C. Shart transports:	Significantly Sector	Someonet Senter	Same As	Signature Wares	West
comments C. Both tran	ماد ماد	and smooth	More sub	the switch	5-2- 1
to elliptical. PEEK	to PE Fook like	(1), PE to el	ipital is nice		
4. Flexibility of shaft:	<u></u>		***		
A, Proximal shart:	Sig <del>raficantly</del> Sector Cl	Somewhile Bester O	Şame As O	Sommunat Worse C)	Signifi War O
B. Distal shart	Significantly	Same		Someone	Signal.
Same as 2	Sector C	Seter O	0	3	G
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Date:

6/21/94

Title:

Coax w/PEEK - Elliptical

Objective:

To evaluate these catheters ( with improved proximal balloon seal and

guidewire movement) versus the catheters in the previous heart model. Ref pg.

Procedure: Note: Ref drawing for dimensions

Tooling:

.011, .017, .018, .024, .026, .028 .031 and .040 Teflon coated mandrels.

.025, .031, .039, 043 and .048 Teflon capture tubing.

Razor blades, Hot box, and Induction heater

Materials:

Part Number Comments Description 75/25 Alathon/LDPE Elliptical dual lumen N/A R&D Ext. # 12-083 Alathon 6210 Intermediate shaft Ext # V-466-1 Graphite IΜ PEÉK 381G Stiff Shaft Vendor# 02-149 MC500419-02 N/A Shaft adaption cup Standard ACS part IM adaption cup Standard ACS part MC500323 Centerport MC500319 Standard ACS part Nose cone RM500219 Two arm Ext. # V-466-1 Graphite Distal tip Material PE 600 Balloon 3.0mm Edge Shrink tubing SA500082-03 RM500340 Gold Bands Loctite RM60563 414 420 RM60124 Loctite 350 RM60562 Loctite

#### Assembly Instructions: (Distal Elliptical)

Cut approximately 40 cm of the elliptical shaped tubing.

- Place a .018" Teflon Mandrel in the guide wire lumen and a .015 Teflon mandrel in the inflation lumen.
- Neck the material down to  $.026 \times .045 +/- .001$ .
- Parameters: Temp = 270'f Stretch Speed = 200 Nozzle Speed = 600 Dwell Heat = 5 Dwell Cool = 1 Length = 15cm Trim necked portion to 10cm.
- Cut a 2-3mm notch in the inflation lumen at the distal tip of the necked material. (fig 1)

#### Distal Tip:

Cut the graphite to approximately 20 cm.

Neck the graphite to .021 OD using an autonecker.

Parameters: Temp = 290' f Stretch Speed = 400 Nozzle Speed = 200 Length = 10cm

Slide the gold band over the necked portion.

- Recover the graphite up to the gold band using a .024 capture tube and Hot Box, at 350° f Using a .028" sheath and a Hot Box at 350° f and 60-70 psi expand 1 cm. Remove material from the sheath and trim to 5mm.
- Insert a .017" Teflon mandrel through the graphite and the guidewire lumen of the elliptical material.
- Fuse the graphite to the elliptical dual lumen using a .026 capture tube and Hot Box at 350° f

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#### Balloon Seal:

Expand proximal balloon shaft in a .048 ID capture tube.

Trim to 7mm

Insert a .015 mandrel into the inflation lumen.

Slide .039 oval split sheath onto catheter.

Slide sheath over proximal portion of the balloon and heat seal at 350° f

Flatten with a flat smooth block

Remove inflation/deflation mandrel.

Tip seal using a "Balloon Buncher Tip Sealer"

Parameters: Temp = 340' f Hot Stretch = 0003 Dwell = 0006 Pretension =

#### Proximal End:

Trim assembly from the gold band to the proximal end of the elliptical shaped tubing 35cm. Insert two-.018 Teflon coated mandrels into both lumens.

Neck using an autonecker.

Parameters: Temp = 270°f Stretch Speed = 200 Nozzle Speed = 600 Dwell Heat

= 5 Dwell Cool = 1 Length = 1.5cm (trim to 1cm)

Parameters: Temp = 270°f Stretch Speed = 200 Nozzle Speed = 600 Dwell Heat

Remove the mandrels and Insert a 4.5cm piece of Polyimide into the inflation lumen. Tack the Polyimide into place with a drop of Loctite 420.

## Inner Member Assembly:

Cut a 125cm piece of Graphite inner member material.

Insert a .017 mandrel through the Graphite.

- Neck the Graphite to .021 OD using an autonecker.

  Parameters: Temp = 290° f Stretch Speed = 400 Nozzle Speed = 200

  Length = 1cm (trim to 4mm)
- Flare the guidewire lumen with a .025 mandrel 1mm.

Insert the necked graphite into the flared guidewire lumen.

Insert a .012 mandrel into the Polyimide.

- Bond the Graphite to the dual lumen elliptical material using a .039 oval capture tube or silicone Parameters: Temp = 350° f (Hot Box)

- Remove the .012 mandrel from the Polyimide.

## Proximal Shaft Assembly:

Cut a 110cm piece of PEEK.

Expand one end of the PEEK, 1cm in a .043 capture tube using a Hot Box at 350° f (ID should

- Trim the expanded portion 5-6mm

Cut the PEEK 102 cm from the proximal end of the expanded portion.

Slide the PEEK over the Graphite IM and elliptical material and bond using Loctite 420 Note: do not allow the adhesive to wick into the Polyimide tubing. Note: do not force the unexpanded PEEK over the Inflation lumen.

#### Two-Arm Assembly:

Trim the graphite 3cm from the proximal end of the PEEK.

Slide the nosecone, outer member adaption cup, and twoarm over the PEEK.

Bond and inner member adaption cup to the graphite using 3.0 mm x 1cm shrink tubing on a Hot Box at 350° f. Note: use a .018 Teflon mandrel in the graphite.

Attach the IM cup to the twoarm with a centerport.

Slide the outer member cup up toward the twoarm and wick in UV cure Loctite 350
 Attach the OM cup to the twoarm and tighten the nosecone and centerport

UV cure on each side of the nosecone for 50 seconds.

#### Final Assembly:

Trim tip to 3.0mm

Tip Sand

- Microglide and Sheath

Conclusion: These catheters performed better then the catheters in the previous heart model. The proximal seals were improved by maintaining a flat geometry. This was accomplished by using a smooth flat block to flatten the bond area while it's in the capture tube. Although these catheters were better then the previous elliptical units they were not as good as the coaxial and could use some improvements. The guidewire movement was better than before but again not as good as the coaxial. The catheters did not track as well and seem to prolapse in the Aorta when the guide was backed out and force was applied to the catheter.

Recommendation: It was recommended that we evaluate different materials transitions and dimensions to reduce the prolapsing. Refine the inner member junction to improve wire movement. Another heart model was tentatively scheduled. (see heart model evaluation notes)